Roll No:

MPHARM
(SEM I) THEORY EXAMINATION 2021-22
MODERN PHARMACEUTICS

Time: 3 Hours ***Total Marks: 75***

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	How does self-emulsifying drug delivery works?
b.	Summarize the objectives of screening of drug-excipient compatibility.
c.	Which type of process validation is rarely used?
d.	List two objectives of pharmaceutical validation.
e.	Why budget and cost control are important for pharmaceutical companies?
f.	Classify various sales forecasting techniques.
g.	What is ejection force in tablet compression?
h.	How is compaction different from compression?
i.	Give the formula for standard deviation.
j.	What is the relevance of f1 and f2 factor in drug dissolution studies?

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a. In a preclinical study, animal was treated with two antihypertensive experimental drugs and a control drug, with 12 animals randomly assigned to the three groups, four per group. One animal died from a nondrug related cause and was lost to the experiment. The results (change in blood pressure from baseline) are shown in table below. Are the treatment means different, or do the observed difference merely reflect the inherent variation of the animal response to such treatments? Assume that variances within each group are equal, and that the data are independent and normally distributed.

Table: Change of blood pressure in pre-clinical study comparison Two drugs and control.

Drug 1	Drug 2	Control
15	8	
12	14	16
19	13	20
11	6	22

The cutoff point for significance at the 5% level for $F_{2,8}$ is 4.46.

b. Illustrate the procedure to optimize process parameters using factorial design and simplex lattice.

c. Illustrate the compaction profiles using relevant graphs and equations used to interpret the nature of tablet excipient and API in tablet compression studies.

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SECTION C

3. **Attempt any *five* parts of the followir g:** **7 x 5 = 35**

a.	Two batches of tablets were prepared using disintegrating agents A or B. Dissolution was determined on randomly selected tablets with the following results: Disintegrants A: 45,50,47,43,41,49,35; $\bar{x}$ = 44.29 and S^2 = 26.9. Disintegrant B: 38,47,42,39,32,36,41; $\bar{x}$ = 39.29 and S^2 = 35.57. Find whether there the difference in dissolution data is significant. The tabulated t at 5% level with 12 df is 2.18.
b.	Demonstrate the prediction of shelf life based on kinetics of stability testing using relevant equations and plot.
c.	Compute prospective and retrospective validation in context to the situations in which they are applied.
d.	Explain current good manufacturing practice for finished pharmaceuticals.
e.	Illustrate the process to validate coated and uncoated tablet dosage form using appropriate critical process parameters.
f.	Explain how TQM is applied in pharmaceutical industry.
g.	Demonstrate the role of differential scanning calorimetry for the screening of drug-excipient compatibility using industry relevant case studies.